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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/858,349 | 05/15/2001 | Daniel Plaksin | 87534-2800 | 2778 |

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WINSTON & STRAWN
PATENT DEPARTMENT
1400 L STREET, N.W.
WASHINGTON, DC 20005-3502

EXAMINER

WESSENDORF, TERESA D

| ART UNIT | PAPER NUMBER |
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1639

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/858,349

Applicant(s)

PLAKSIN, DANIEL

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 34, 36-44, 46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 11-18, 20, 38, 39 and 41-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 10, 19, 34-37, 40, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of Claims

Claims 1-20, 34, 36-44 and 46-47 are pending in the application.

Claims 21-33, 35 and 45 have been cancelled in the 5/15/03 Amendment.

Claims 6-8, 11-18, 20, 38-39 and 41-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

In view of the amendments to the claims, the claims under examination are 1-5, 9-10, 19, 34-37, 40 and 46-47.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 9-10, 19, 34-37, 40 and 46-47, as amended, rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

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the application was filed, had possession of the claimed invention.

In view of the amendments to the claims the previous rejection no longer applies. However, the amended claims are rejected as follows:

The specification does not provide a sufficient description of a polypeptide with a charged residue. It is not apparent from the disclosure as to the complete sequence or a sequence containing the charged residue. A charged residue may be any negative or positively charged residue that may be natural or synthetic. The single residue Lys described in the specification would not be considered as adequate to describe the unduly large field of a charged residue in a polypeptide sequence. It is not apparent from the single residue, Lys whether any other charged residue would confer a soluble or stable polypeptide able to bind an antigen. It is well known in the art that a change in so much a single residue can result in an unstable polypeptide. Thus, a single residue is not deemed representative of a huge charged residue as claimed due to the high unpredictability in this art. A "written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject

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matter sufficient to distinguish it from other materials".

University of California v. Eli Lilly and Col, 43 USPQ 2d 1398, 1405(1997), quoting Fiers V. Revel, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993). See also University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003).

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 9-10, 19, 34-37, 40 and 46-47, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons advanced in the last Office action.

This rejection has been partly overcome with the amendments to the claims and partly with applicant's arguments. However, the rejection that has not been overcome is maintained and addressed below, as it applies to the newly amended claims.

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Response to Arguments

C. Applicant submits that it is possible to produce the polypeptides in other hosts such as unicellular organisms, whether prokaryotic or eukaryotic, or cell lines from multicellular organisms, whether plant or animal, the latter ranging from insect to mammalian cells (see page 4 line 24 - page 5 line 2). Therefore restricting production to one host merely limits the scope of the claim to one embodiment and is not confusing.

In response, as clearly admitted by applicant, the claim recite for process steps i.e., production of the polypeptide in numerous host organisms. The method by which the compound i.e., polypeptide is produced does not add further limitation to the compound.

1. Claim 1, as amended, is indefinite in the recitation that there is no mutations or modifications in the original VH/VL interface framework. However, the original residue at position 44 is Gly, not Lys. Hence, there is a modification/mutation to the VL/VH interface by the charged residue.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-5, 9-10, 19, 34-37, 40 and 46-47, as amended, are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter for reasons set forth in the last Office action.

Response to Arguments

Applicant states that the certified copy of the Israeli priority 127127 has been submitted in the response dated October 21, 2003. Since the priority is in the English language, hence, the priority date of November 11, 1998 has been established for the claimed subject matter. Applicant submits that even though it is true that the other authors are not inventors, Applicant submits that no such declaration is deemed necessary. The Reiter publication was made after the priority date and is not an effective prior art reference.

In response, while the priority date has been established with the Israeli priority document however, the statement in the specification that "we" presupposes other inventive entity and

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the rejection is not based on the Reiter as prior art.

Applicant's arguments and statements cannot substitute for the declaration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9-10, 19, 34-37, 40 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over del Rio et al (EP 712863) in view of de Wildt (Protein Engineering).

Del Rio et al discloses a polypeptide of a single domain of a heavy chain variable of an antibody molecule having a sequence Fig. 1(b), page 13. The sequence contains gly at position 44, Leu at position 45 and Trp at position 47. Del Rio does not disclose a polypeptide with a charged residue as Lys at position 44. However, de Wildt discloses at page 838, col. 2 that heavy chain with Lys residue has the highest affinity to an antigen. Accordingly, it would have been obvious to one having ordinary

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skill in the art at the time the invention was made to replace the gly residue in the heavy chain polypeptide of del Rio with a charged residue as Lys as taught by de Wildt. The advantage taught by de Wildt that charged residue, specifically Lys results has the highest affinity to antigen would provide the motivation to one having ordinary skill in the art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hong et al disclose a humanized antibody specific for human 4-1BB.

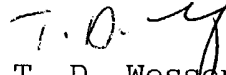
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
August 6, 2004